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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/926,589   | 11/21/2001  | Olivier Rousseaux    | P67341US0           | 1439             |
| 136  | 7590        | 01/22/2004           | EXAMINER            |                  |
| JACOBSON HOLMAN PLLC<br>400 SEVENTH STREET N.W.<br>SUITE 600<br>WASHINGTON, DC 20004 |             |                      | HARTLEY, MICHAEL G  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1616                |                  |

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/926,589

**Applicant(s)**

ROUSSEAU ET AL.

**Examiner**

Michael G. Hartley

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20, 23 and 24 is/are rejected.
- 7) ☒ Claim(s) 21 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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***Response to Amendment***

The preliminary amendment filed 10/14/2003 has been entered. Any previous rejections that are not reiterated herein have been withdrawn.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer (WO 97/01359, US equivalent 5,886,158 relied upon) in view of Uggeri (US 6,177,562), for the reasons set forth in the office action mailed 4/14/2003.

Claims 19, 20, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer (US 6,187,285) in view of Uggeri (US 6,177,562), for the reasons set forth in the office action mailed 4/14/2003.

***Response to Arguments***

Applicant's arguments filed 10/14/2003 have been fully considered but they are not persuasive.

Applicant asserts that Uggeri only teaches "a couple diastereomers" and not a racemic compound as claimed, and therefore, since there are up to 16 stereoisomers in the DOTA analogues taught by Uggeri, as well as, Meyer, there would be no reason to choose a racemic compound, as claimed.

This is not found persuasive as "racemic" has a defined meaning in the art, as shown by any chemical dictionary and supported by applicant's arguments which includes a definition thereof. Uggeri clearly teaches that the MRI contrast agents include racemic compounds, by stating "The present invention relates to the compounds of formula I in the racemic and optically active forms" see for example, the last paragraph in column 2. Thus, applicant's statement that Uggeri does not teach a

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racemic compound is not seen. Also, as supported by Uggeri, such isomers are generally unpatentable over other isomers. An optically active isomer is unpatentable over a prior art racemate or optical isomer in the opposite rotation in the absence of unexpected results. For example, *In re Adamson* (CCPA 1960) 275 F2d 952, 125 USPQ 233; *Brenner v. Ladd*, Comr. Pats. (DCDC 1965) 247 Fsupp 51, 147 USPQ 87 and *In re Williams* (CCPA 1948) 171 F2d 319, 80 USPQ 150. Uggeri discloses contrast agents having the formula set in column 3 (i.e., DOTA analogues) and teaches that racemic compounds of such substituted DOTA analogues are useful as contrast agents for methods of MRI, see column 3, lines 42. A limited number of 16 isomers which are be present would not preclude one of ordinary skill in the art in desiring a racemic compound given that analogous MRI agents are known to be useful as a racemic compound as taught by Uggeri, and such racemic compounds are well known in the art of chemistry and have generally been viewed as structurally obvious.

#### ***Allowable Subject Matter***

Claims 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 19 and 20 are free of the art of record because the prior art fails to teach or suggest the methods of preparing the racemic compounds as claimed, using the combination of pH, temperature and reaction as claimed.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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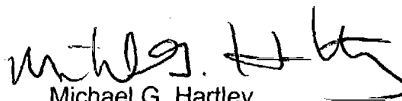
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Starting 2/4/2004, I can be reached at (571)272-0616 and my supervisor can be reached at 571-272-0602.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Michael G. Hartley  
Primary Examiner  
Art Unit 1616

MH  
January 20, 2004